510(k) Summary

per 21 CFR §807.92

AUG 12 2013

Submitter's Name Address	PendraCare International B.V. Van der Waalspark 22 9351 VC Leek The Netherlands FDA Establishment Registration Number 3005635992 Owner / Operator Number: 10041705
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Date prepared	11 July, 2013
Proprietary Name	Convey™ Guiding Catheter
Common Name	Percutaneous Catheter
Classification	Class II, 21 CFR 870.1250
Review Panel	Cardiovascular
Product Code	DQY
Subject Devices	Convey™ 7F Guiding Catheter Convey™ 8F Guiding Catheter
Predicate Devices	Convey™ 5F Guiding Catheter (K120585; August 8, 2012) Convey™ 6F Guiding Catheter (K120585; August 8, 2012)

Device Description	The guiding catheter is a flexible plastic tube featuring a luer hub, a strain relief, a body, an intermediate tip, and a soft tip. The body and the intermediate tip exist of an inner liner (basecoat) and an outer jacket (topcoat) reinforced with a tightly wound stainless steel braid wire in between the layers. The central lumen of the catheter is used for the percutaneous, transluminal passage and placement of guidewires, diagnostic and / or therapeutic (interventional) devices within the vascular system. The distal section of the catheter has a variety of preformed shapes (e.g., Judkins Left (abbreviated as JL), Judkins Right (JR), Amplatz (AL), Multi-purpose, hockey stick) to facilitate placement of the catheter tip in the desired target vessel. Some catheter models feature two (2) small "in-line" side holes in the intermediate tip section to maintain perfusion of the target vessel. This device is a single-use device (i.e., single patient, single procedure, single purpose use). After finalizing the procedure, the catheter is withdrawn, removed and discarded.
Intended Use of Device	The Convey Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.
Indications for Use	The Convey Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.
Substantial Equivalence	The Convey™ 7F Guiding Catheter and Convey™ 8F Guiding Catheter incorporate substantially equivalent device materials and design, packaging materials and design, intended use, fundamental technology (operating principle & mechanism of action), labeling and manufacturing processes and sterilization process as those featured in the legally marketed predicate devices, the Convey™ 5F Guiding Catheter and Convey™ 6F Guiding Catheter (K120585, clearance: August 8, 2012).

Summary of Non-clinical Testing	To support a determination of substantial equivalence, data was collected from non-clinical design verification (bench) tests. The results provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
	The following in-vitro performance tests (following simulated use, if applicable, were completed of the 7F & 8F Convey Guiding Catheter: • Visual Inspection, • Shape Conformance & Shape Retention, • Outer Diameter, • Inner Diameter, • Usable Catheter Length, • Side Hole diameter & positioning, • C-Kink (Bending Kink Diameter), • Euler Kink (Axial Kink Displacement), • Radial Stiffness (Collapse), • Three Point Bending Test (Bending Stiffness Body), • Pull Force Test (after simulated use), • Coating location & length • Coating Integrity – Outer Friction & Wear functional test, • Coating Integrity (after simulated use), • Torque Strength (after simulated use), • Body Strength / Burst Pressure test, • Particulate testing, • Radiopacity / Visibility testing.
Summary of Sterility Testing	• Bacterial Endotoxin-Mediated Pyrogenicity Testing, • Bioburden testing, • Ethylene Oxide Residual Testing.

Summary of Biocompatibility Testing	The Biocompatibility for the 7F & 8F Convey Guiding Catheter was leveraged from the biocompatibility tests completed on the 5F & 6F Convey™ Guiding Catheter. The following tests were conducted:
	• ISO 10993-4: Haemocompatibility:
	  o Hemolysis
	  o In vitro Haemocompatibility
	  o Coagulation Tests Prothrombin Time Assay-PT
	  o Coagulation Unactivated Partial Thromboplastin Time Assay-UP
	• ISO 10993-5: Cytotoxicity – MEM-elution (USP<87>)
	• ISO 10993-7: Ethylene Oxide Sterilization Residuals
	• ISO 10993-10: Sensitization (USP<1184>)
	• ISO 10993-10: Irritation / Intracutaneous Reactivity (USP <88>)
	• ISO 10993-11: Acute Systemic Toxicity (USP <88>)
	• ISO 10993-11: Material Mediated Pyrogenicity (USP <151>)
	• USP <661>: Packaging Plastic Containers Leachables

Summary of Clinical Testing	Since the modifications do not have an impact on the indications for use and on the safety and performance of the device, a Clinical Evaluation Study was not regarded for these devices.
Conclusion	In summary, the modifications in the subject devices Convey™ 7F Guiding Catheter and Convey™ 8F Guiding Catheter do not affect the intended use and does not alter the fundamental scientific technology of the device. The subject devices Convey™ 7F Guiding Catheter and Convey™ 8F Guiding Catheter are substantial equivalent to the predicate devices Convey™ 5F Guiding Catheter (K120585, dated 8 August 2012) and Convey™ 6F Guiding Catheter (K120585, dated 8 August 2012) with respect to the intended use, fundamental technology, i.e., operating principle, device materials, design, packaging materials & configuration, labeling, manufacturing & sterilization processes and sterility assurance level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 12, 2013

Pendracare International, B.V.
% Mr. Tom Nolan
Managing Director
Corvitex Corporation
7205 Laketree Dr
Raleigh, NC 27615

Re: K132197
Trade/Device Name: Convey™ 7F Guiding Catheter, Convey™ 8F Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 11, 2013
Received: July 16, 2013

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132197

Device Name: Convey™ 7F Guiding Catheter,

Convey™ 8F Guiding Catheter

Indications for Use:

The Convey Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number: K132197